SEP 2 5 2001

K012411

HP-ONE™ 510k SUMMARY

HP-ONE is a trademark of GI Supply division of Chek-Med Systems Inc.

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1. PRODUCT NAME: *HP-ONE*™

2. CLASSIFICATION NAME: Campylobacter pylori test - CODE 83LYR

3. INTENDED USE:
HP-ONE detects the urease enzyme for the presumptive identification of *Helicobacter pylori* in gastric mucosal biopsies. It is intended for *in-vitro* diagnostic use only.

3. SUMMARY:
Helicobacter pylori has now been shown to be the causative agent in most instances of acute type B gastritis (1). And, it is now known that, in the absence of aspirin, non-steroidal anti-inflammatory drugs or hyper-secretory states, the bacteria is directly related to peptic ulcer disease such as duodenal and benign gastric ulcers (2). There is epidemiological data linking the presence of the *H. pylori* with gastric cancer and the low-grade mucosal associated lymphoid tissue (MALT) lymphoma (3,4). The eradication of *H. pylori* gastritis by antibiotics has been shown to cure peptic ulcers and prevent recurrence (4,5).

4. PRINCIPLE:
A gastric mucosal endoscopic biopsy is placed in the HP-ONE tray well and a reagent containing urea, hydrogen peroxide, a pH dye indicator, and an acidic buffer is placed over the biopsy specimen. A bubbling reaction occurs as catalase breaks down the peroxide.
If *H. pylori* is present, the urease in *H. pylori* converts the urea to ammonia which raises the pH and changes the color of the reagent, indicating a positive test.

$$(NH_2)CO + H_2O \xrightarrow{\text{urease}} NH_3 + HCO_2$$

urea ammonia

5. STORAGE/STABILITY:
The HP-ONE reagent is stable and provides accurate results for up to 12 months if refrigerated at 2-8°C. Alternatively, the reagent can be stored at room temperature (18-24°C) but the shelf life will be shortened to 3 months. If stored at room temperature, mark the date of receipt on the label and do not use beyond 3 months. Do not expose to heat or bright light. Do not use the test if the color is not a yellow or yellow-orange color or if the test is past the expiration date. Each HP-ONE reagent bottle contains an expiration date and lot number to permit tracking.

6. SUBSTANTIAL EQUIVALENCE AND DIFFERENCES TO PREDICATE DEVICE:
The principle of HP-ONE is substantially equivalent to HP-Fast another product marketed by GI-Supply. They share the same operating principal, but HP-ONE has technical differences from HP-Fast. HP-ONE is a liquid rather than an agar gel and also has a lower pH than HP-Fast. HP-One also contains hydrogen peroxide that acts as a preservative and helps to expedite the urease reaction when *H. pylori* is present.

7. SUMMARY OF HP-ONE PERFORMANCE CHARACTERISTICS:
In the clinical study of 117 patients with possible peptic ulcer disease, 65 demonstrated positive histological criteria (presence of *H. pylori* organisms upon staining) for *Helicobacter pylori* and 52 did not demonstrate the criteria. HP-ONE agreed with the positive histological diagnosis in 60 cases (92.3%) and agreed with the negative diagnosis in all 52 (100%) of the cases. *This data provides a relative sensitivity of 92.3% and a relative specificity of 100%.*

	True +	*False +*
HP-One Positives	60	0
	False -	*True -*
HP-One Negatives	5	52

Histology Positives = 65
Histology Negatives = 52

HP-One Sensitivity = 92.3%
HP-One Specificity = 100%
Positive Predictive Value = 100%
Negative Predictive Value = 91.23%

HP-One correctly diagnosed 66.67% of the positives within 5 minutes and 83.3% of the positives by 15 minutes. There were no false positives when diagnosed within the one-hour final reading of the test.

8. MEDICAL DEVICE REPORTS / ADVERSE REACTIONS ENCOUNTERED:
To date, no MDR's have been filed and no patient adverse reactions have been encountered.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 2 5 2001

Mr. Frank Carter
President
GI Supply, Division of Chek-Med Systems Inc.
200 Grandview Avenue
Camp Hill, PA 17011

Re: K012411
Trade/Device Name: *HP–ONE* Rapid Urea Assay
Regulation Number: 21 CFR 866.3110
Regulation Name: Campylobacter Pylori
Regulatory Class: I
Product Code: LYR
Dated: July 27, 2001
Received: July 30, 2001

Dear Mr. Carter:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 8.2 Intended Use Certification

510k INDICATION FOR USE STATEMENT

510(k) Number (if known): K012411

Device Name: HP-ONE

Applicant Name: GI Supply division of Chek-Med Systems Inc.

Indication for Use: HP-ONE is for in-vitro diagnostic use only. It is intended to detect the urease enzyme of *Helicobacter pylori* and provide a presumptive diagnosis of *H. pylori* gastritis.

GI Supply/Chek-Med Signature: _____ Date: 7-26-01
Frank Carter - CEO

_____
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012411

✓ Prescription use